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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,064	02/13/2006	Akira Shimotoyodome	282148US0PCT	7467
22850 7590 01/04/2010 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER SZNAIDMAN, MARCOS L				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/568,064

Applicant(s)

SHIMOTOYODOME ET AL.

Examiner

MARCOS SZNAIDMAN

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 7-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5 and 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to applicant's request for continued examination filed on July 6, 2009 and the reply filed on October 26, 2009 in response to a Restriction/Election requirement.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission and amendments filed on April 6, 2009, has been entered.

Election/Restrictions

Applicant's election with traverse of the species gallocatechin in the reply filed on October 26, 2009 is acknowledged. Applicant's arguments are persuasive, so the election requirement is withdrawn.

Status of Claims

Amendment of claim 5 and addition of claims 10-15 is acknowledged.

Claims 1-5 and 7-15 are currently pending and are the subject of this office action.

Claims 1-4 and 7-9 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 4, 2008.

Claims 5 and 10-15 are presently under examination.

Priority

The present application is a 371 of PCT/JP04/13652 filed on 09/17/2004, and claims priority to foreign application: JAPAN 2003-326140 filed on 09/18/2003.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

Rejections and/or Objections and Response to Arguments

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not

Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112 (New Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 10-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 5 and 10-15 recite the limitation: "consisting essentially of". However, a careful review of the specification and the claims, as originally filed, does not appear to lend support for the limitation: "consisting essentially of". Moreover, the specification does not appear to have contemplated the exclusion of any particular ingredients, nor provided any criteria for determining if a given component "materially affects" the claimed composition.

Note: although claims 5, 10-15 recite the limitation "consisting essentially of" it is being interpreted as "comprising". MPEP 2111.03 states that: for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear

indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising" (see above written description rejection).

Claim Rejections - 35 USC § 102 (New Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 5, 10, 12 and 14-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Lines et. al. (US 2004/0126461).

Claim 5 recites a method for improving endurance, which comprises administering to a subject in need thereof an effective dose of a composition comprising (see above discussion) catechins, wherein said subject in need thereof is a subject who needs to do exercise requiring endurance or labor requiring repeated muscle exercise.

Claims 10, 12 and 15 further limit claim 5, wherein the catechin is: epigallocatechin.

Claims 10 and 14 further limit claim 5, wherein the catechin is:
epigallocatechingallate.

For claims 5, 10, 12 and 14-15, Lines teaches a method for enhancing physical performance (i.e. improving endurance, see paragraph [0003]), the method comprising administering to a subject in need thereof a composition comprising at least one of a green tea extract containing among others: epigallocatechin gallate, epicatechin gallate, epicatechin and epigallocatechin (see claims 22-29).

Lines further teaches that the individuals in need thereof are for example athletes that are involved in prolonged systematic exercise (i.e. repeated muscle exercise, see paragraph [0002]).

Claim Rejections - 35 USC § 103 (new Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lines et. al. (US 2004/0126461) in view of Demeule et. al. (Current Medicinal Chemistry (2002) 2:441-463).

Claim 11 further limits claim 10, wherein the catechin is at least gallocatechin

Claim 13 further limits claim 10, wherein the catechin is at least
gallocatechingallate

Lines teaches all the limitations of claims 11 and 13 (see above 102 rejection) except for the catechins gallocatechin and gallocatechingallate. However, Demeule

teaches that gallocatechin and gallocatechingallate are catechins like epigallocatechin gallate, epicatechin gallate, epicatechin and epigallocatechin that are found in tea leaves (see page 443 Figure 1) and that they all share common structural and biological properties (see entire document).

Since Lines teaches a method of improving endurance with the catechins: epigallocatechin gallate, epicatechin gallate, epicatechin and epigallocatechin , and since Demeule teaches that gallocatechin and gallocatechingallate are catechins, at the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to substitute one functional equivalence (any catechin) for another (gallocatechin and gallocatechingallate) with an expectation of success, since the prior art establishes that both function in similar manner, thus resulting in the practice of claims 11 and 13, with a reasonable expectation of success.

Withdrawn Rejections and/or Objections

Claims rejected under 35 USC 102(b)

Due to Applicant's amendments, the 102(b) rejection is moot.

Rejection under 35 USC 102(b) is withdrawn.

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1612
December 14, 2009.